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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/511,711 | 04/07/2005 | Niklas Ahlborg | 102672-103 | 6727 |
| 27267 | 7590 | 07/12/2006 | EXAMINER | |
| WIGGIN AND DANA LLP ATTENTION: PATENT DOCKETING ONE CENTURY TOWER, P.O. BOX 1832 NEW HAVEN, CT 06508-1832 | | | GRUN, JAMES LESLIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/511,711 | Applicant(s) AHLBORG ET AL. | |
| | Examiner James L. Grun | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9,12,14-26,32-36,41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,12,14-26,32-36,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The amendment filed 25 April 2006 is acknowledged and has been entered. Claims 41 and 42 are newly added. Claims 10, 11, 13, 27-31, 37-40 have been cancelled. Claims 1-9, 12, 14-26, 32-36, 41 and 42 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9, 12, 14-26, 32-36, 41 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, it is not clear what applicant intends as the “engineered protein” because the second wherein clause would appear redundant or superfluous unless applicant intends engineered antibody as encompassed.

In claim 35 and claims dependent thereupon, it is not clear what applicant intends as the “engineered protein” because the second wherein clause would appear redundant or superfluous unless applicant intends engineered antibody as encompassed.

Applicant's arguments filed 25 April 2006 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

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Claims 1-9, 12, 32-36, 41, and 42 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Self (US 4,595,655) for reasons of record in the prior rejection of the similar subject matter of claims 1-10 and 32-40. In addition to the teachings of the reference set forth previously, the reference teaches that the non-antibody receptors can be produced synthetically (see e.g. col. 3).

Claims 1-8, 12, 32-36, 41, and 42 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Canfield et al. (US 5,284,778) for reasons of record in the prior rejection of the similar subject matter of claims 1-8, 10, and 32-40. In addition to the teachings of the reference set forth previously, the reference teaches that the non-antibody receptors can be produced synthetically (see e.g. col. 6).

Applicant's arguments filed 25 April 2006 have been fully considered but they are not deemed to be persuasive. Applicant urges that the references do not teach receptors or engineered proteins. This is not found persuasive for the reasons set forth above. In this regard, the examiner considers a synthetic receptor as "engineered" as there is nothing in the claims that limits the manner of engineering or distinguishes an "engineered protein" from those provided by the references.

Claims 1-4, 6-8, 12, 14-26, 32, 35, 36, and 41 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Hansson et al. (Immunotechnol. 4: 237, 1999) for reasons of record in the prior rejection of the similar subject matter of claims 1-4, 6-8, 10-26, 32, and 35-40.

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Claims 1-4, 6, 8, 12, 14-26, 32, 35, 36, and 41 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ljungqvist et al. (WO 00/63243) for reasons of record in the prior rejection of the similar subject matter of claims 1-4, 6, 8, 10-26, 32, and 35-40.

Applicant's arguments filed 25 April 2006 have been fully considered but they are not deemed to be persuasive. Applicant urges that the references do not teach the purpose of the method as indirectly detecting the presence of the human factor VIII in a complex biological fluid sample. These are not found persuasive because a recitation of intended use is accorded patentable weight only to the extent that it results in a manipulative difference as compared to the prior art; in the instant case the intended use does not affect the components or steps as instantly positively claimed in any way which distinguishes over the subject matter taught or suggested by the references.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ljungqvist et al. (US 6,602,977) contains essentially the identical disclosure of Ljungqvist et al. (WO 00/63243).

Foresman et al. (US 5,801,064) disclose scFv-autoantigen-autoantibody sandwiches.

Samuel et al. (US 5,242,799) disclose lectin-antibody sandwich immunoassays.

Bosslet et al. (US 5,643,731) disclose universal solid phase or universal conjugate reagents in which pairs of leucine zipper peptides are bound to specific binding partners such as antibodies, lectins, receptors, etc. (see e.g. Figs.).

Drukier (WO 01/81924) discloses a sandwich assay for detection of a ligand using a non-antibody aptamer to which the ligand binds and an antibody specific for the ligand (see e.g. pages 11-12, 27, and 42-44; claims 43-62). Either the aptamer or the antibody can be labeled with a detectable marker. One of the pair of ligand binding molecules is affixed to a solid support chip.

Yu et al. (US 6,197,526) disclose a sandwich assay for detection of human factor VIII using a non-antibody human factor VIII binding molecule and an antibody specific for human factor VIII (see cols. 8-12 and 15).

Cozzette et al. (US 5,837,446) disclose sandwich assays for detection of a variety of analytes (cols. 47-50), including Respiratory Syncytial Virus.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James L. Grun, Ph.D.
June 27, 2006


LONG V. LE 07/06/06
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